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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Modified Form 1449/PTO	Application Number	10/616,649
		Filing Date	07/09/03
		First Named Inventor	Chiao
		Group Art Unit / Conf. No.	1614 / 9975
		Examiner Name	Not Yet Assigned
		Attorney Docket Number	24852-501 CIP2

U.S. PATENT DOCUMENTS							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date
MG	A25*	4,690,918	09/01/87	Beppu, et al.			
↓	A26*	5,654,333	08/05/97	The United States of America as represented by the Department of Health and Human Services			
	A27*	6,239,176	05/29/01	Beacon Laboratories, Inc. et al.			
	A28*	6,262,116	07/17/01	Sloan-Kettering Institute for Cancer Research			
	A29*	6,451,334	09/17/02	Pemine			
	A30*	6,495,719	12/17/02	CircaGen Pharmaceutical			
	A31*	2003/0114525	06/19/03	Kammer, et al.			
↓	A32*	2004/0132643	07/08/04	Fojo, et al.			
	A33*	2004/0167184	08/26/04	Wiech, et al.			
MG	A34	6,495,719	12/17/02	Lan-Hargest, et al.			

FOREIGN PATENT DOCUMENTS							
Exam Initials	Cite No.	Foreign Patent Document Office	Number	Name of Patentee(s) or Applicant(s)	Date of Publication	English Yes	No
MG	B14*	WO	98/39965	Beacon Laboratories, LLC	09/17/98	X	
↓	B15*	WO	02/15921	The Government of the United States of America	02/28/02	X	
MG	B16*	WO	02/055017	Wake Forest University	07/18/02	X	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
MG	C83*	"Aton Pharma, Inc. Announces Initiation of Two Phase II Trials to Evaluate Efficacy of HDAC Inhibitor SAHA", October 30, 2002.
↓	C84*	"Aton Pharma, Inc. Announces Phase I Clinical Trial of SAHA in Advanced Leukemias", July 1, 2003.
	C85*	"Aton Pharma, Inc. Appoints Judy H. Chiao, M.D., as Vice President; Oncology Clinical Research and Development", September 20, 2002.
	C86*	"Aton Pharma, Inc. Presents Phase I Trial Data of Anti-Cancer Agent SAHA in Patients with hematological Malignancy at ASCO", June 2, 2003.
↓	C87*	"Aton Pharma, Inc. Presents Phase I Trial Data on Anti-Cancer Agent SAHA at EORTC/NCI/AACR Symposium", November 21, 2002.
MG	C88*	"Aton Pharma, Inc. Received Orphan Drug Designation for SAHA in Multiple Myeloma and Initiates Phase I

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
		Trial, October 13, 2003.
MG	C89*	*Aton Pharma, Inc. Reports on Phase I Trial of SAHA, August 14, 2002.
	C90*	Adhikari, D et al., Proceedings of the American Association for Cancer Research Annual Meeting, (1998), Vol. 39, p 312, "Radiosensitization of Lymphoma Cell Lines by Sodium Butyrate".
	C91*	Alexandrov, I et al., FEBS Letters, (1998), Vol. 434, pp 209-214, "Sodium Butyrate Suppresses Apoptosis in Human Burkitt Lymphomas and Murine Plasmacytomas Bearing c-myc Translocations".
	C92*	Almenara, J et al., Leukemia (2002), Vol. 16, pp 1331-1343, "Synergistic Induction of Mitochondrial Damage and Apoptosis in Human Leukemia Cells by Flavopiridol and the Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid (SAHA)".
	C93*	Amin HM et al., British Journal of Haematology (2001), Vol. 115, pp 287-297, "Histone Deacetylase Inhibitors Induce Caspase-Dependent Apoptosis and Downregulation of Daxx in Acute Promyelocytic Leukaemia with t(15;17)".
	C94*	Aron, JL et al., Blood (2003), Vol. 102, No. 2, pp 652-658, "Depsipeptide (FR901228) Induces Histone Acetylation and Inhibition of Histone Deacetylase in Chronic Lymphocytic Leukemia Cells Concurrent With Activation of Caspase 8-mediated Apoptosis and Down-Regulation of c-FLIP Protein".
	C95*	Benoit, NE et al., Immunopharmacology, (1996), Vol. 35, pp 129-139, "Increased inhibition of Proliferation of Human B Cell Lymphomas Following Ligation of CD40, and Either CD19, CD20, CD95 or Surface Immunoglobulin".
	C96*	Bode, J et al., Journal of Interferon Research, (1982), Vol. 2, No. 2, pp 159-166, "Links Between Effects of Butyrate on Histone Hyperacetylation and Regulation of Interferon Synthesis in Namalva and FS-4 Cell Lines".
	C97*	Buckley, AR et al., Cell Growth & Differentiation (1996), Vol. 7, pp 1713-1721, "Alterations in pim-1 and c-myc Expression Associated with Sodium Butyrate-Induced Growth Factor Dependency in Autonomous Rat Nb2 Lymphoma Cells".
	C98*	Buckley, AR et al., Proceedings of the American Association for Cancer Research Annual Meeting, (1997), Vol. 38, p 193, "Reversal of Apoptosis Resistance by Butyrate in rat Nb2 Lymphoma Cells".
	C99*	Byrd, JC et al., Blood (1999), Vol. 94, No. 4, pp 1401-1408, "Depsipeptide (FR901228): A Novel Therapeutic Agent with Selective, In Vitro Activity Against Human B-Cell Chronic Lymphocytic Leukemia Cells".
	C100	Cao, et al. (2001), Am. J. Respir. Cell Mol. Biol., 25:562-8, "Histone Deacetylase Inhibitor Downregulation of bcl-xl Gene Expression Leads to Apoptotic Cell Death in Mesothelioma".
	C101*	Carducci, MA et al., Clinical Cancer Research (2001), Vol. 7, No. 10, pp 3047-3055, "A Phase I Clinical and Pharmacological Evaluation of Sodium Phenylbutyrate on an 120-h Infusion Schedule".
	C102*	Dear, AE et al., Biochimica et Biophysica Acta, (2000), Vol. 1492, pp 15-22, "The Novel Anti-Tumour Agent Oxamflatin Differentially Regulates Urokinase and Plasminogen Activator Inhibitor Type 2 Expression and Inhibits Urokinase-Mediated Proteolytic Activity".
	C103*	Desai, D et al., Anticancer Research (2003), Vol. 23, pp 499-504, "Chemopreventive Efficacy of Suberoylanilide Hydroxamic Acid (SAHA) Against 4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)-Induced Lung Tumorigenesis in Female A/J Mice".
	C104*	Dhordain, P et al., Nucleic Acids Research, (1998), Vol. 26, No. 20, pp 4645-4651, "The LAZ3(BCL-6) Oncoprotein Recruits a SMRT/mSIN3A/Histone Deacetylase Containing Complex to Mediate Transcriptional Repression".
	C105*	Edelman, MJ et al., Cancer Chemotherapy and Pharmacology (2003), Vol. 51, pp 439-444, "Clinical and Pharmacologic Study of Tributyrin: An Oral Butyrate Prodrug".
	C106*	Feinman, R et al., Blood (2002), Vol. 100, No. 11, pp Abstract 3195, "The Histone Deacetylase Inhibitor, Suberoylanilide Hydroxyamic Acid, Induces Apoptosis of Multiple Myeloma Cells".
	C107*	Fillpovich, I et al., Biochemical and Biophysical Research Communications, (1994), Vol. 198, pp 257-265, "Butyrate Induced Apoptosis in Lymphoid Cells Preceded by Transient Over-Expression of HSP70 mRNA".
	C108*	Foss, FM et al., Blood, (1993), Vol. 82, No. 10, Suppl. 1, p 564A, "Biomodulatory Effects of Butyric Acid Derivatives on Leukemia and Lymphoma Cells".
MG	C109	Gediya, et al., J. Med. Chem. (2005), Vol. 48, pp 5047-5051, "A New Simple and High-Yield Synthesis of Suberoylanilide Hydroxamic Acid and Its Inhibitory Effect Alone or in Combination with Retinoids on Proliferation

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
		of Human Prostate Cancer Cells".
MG	C110*	Gelmetti, V et al., Molecular and Cellular Biology (1998), Vol. 18, No. 12, pp 7185-7191, "Aberrant Recruitment of the Nuclear Receptor Corepressor-Histone Deacetylase Complex by the Acute Myeloid Leukemia Fusion Partner ETO".
	C111*	Gerblitz, A, Oncogene, (1999), Vol. 18, pp 1745-1753, "Deregulation of the Proto-Oncogene c-myc Through t(8;22) Translocation in Burkitt's Lymphoma".
	C112*	Gilbert, J et al., Clinical Cancer Research (2001), Vol. 7, No. 8, pp 2292-2300, "A Phase I Dose Escalation and Bioavailability Study of Oral Sodium Phenylbutyrate in Patients with Refractory Solid Tumor Malignancies".
	C113*	Grisolano, JL et al., Proceedings of the National Academy of Sciences (2003), Vol. 100, No. 16, pp 9506-9511, "An Activated Receptor Tyrosine Kinase, TEL/PDGFBetaR, Cooperates with AML1/ETO to Induce Acute Myeloid Leukemia in Mice".
	C114*	Harris, NL et al., Blood (1994), Vol. 84, No. 5, pp 1361-1392, "A Revised European-American Classification of Lymphoid Neoplasms: A Proposal From the International Lymphoma Study Group".
	C115*	Jaboin, J et al., Cancer Research (2002), Vol. 62, No. 21, pp 6108-6115, "MS-27-275, an Inhibitor of Histone Deacetylase, Has Marked in Vitro and in Vivo Antitumor Activity against Pediatric Solid Tumors".
	C116*	Kurita-Ochiai, T et al., Infection and Immunity, (1998), Vol. 66, No. 6, pp 2587-2594, "Volatile Fatty Acid, Metabolic By-Product of Periodontopathic Bacteria, Induces Apoptosis in WEHI 231 and RAJI B Lymphoma Cells and Splenic B Cells".
	C117*	Liu, Z et al., Journal of Cancer Research and Clinical Oncology, (1998), Vol. 124, pp 541-548, "Synergistic Effect of Epstein-Barr Virus and Tumor Promoters on Induction of Lymphoma and Carcinoma in Nude Mice".
	C118*	Madisen, L et al., Molecular and Cellular Biology, (1998), Vol. 18, No. 11, pp 6281-6292, "The Immunoglobulin Heavy Chain Locus Control Region Increases Histone Acetylation along Linked c-myc Genes".
	C119*	Niitsu, N et al., Molecular Pharmacology, (2000), Vol. 58, pp 27-36, "Anticancer Derivative of Butyric Acid (Pivalyloxymethyl Butyrate) Specifically Potentiates the Cytotoxicity of Doxorubicin and Daunorubicin Through the Suppression of Microsomal Glycosidic Activity".
	C120*	Orr, D et al., 2000 ASCO Annual Meeting, Abstract No. 763, "Phase I Pharmacokinetic (PK) Study of CI-994 in Combination with Gemcitabine (GEM) in Patients with Advanced Solid Tumors".
	C121*	Polack, A et al., The EMBO Journal, (1993), Vol. 12, No. 10, pp 3913-3920, "Regulatory Elements in the Immunoglobulin Kappa Locus Induce c-myc Activation and the Promoter Shift in Burkitt's Lymphoma Cells".
	C122*	Rezuke, WN et al., Clinical Chemistry (1997), Vol. 43, No. 10, pp 1814-1823, "Molecular Diagnosis of B- and T-cell Lymphomas: Fundamental Principles and Clinical Applications".
	C123*	Rottlieb, C et al., International Journal of Cancer, (1995), Vol. 62, pp 697-702, "Among 17 Inducers of Differentiation Only Sodium Butyrate Causes a Permanent Down-Regulation of c-myc in Burkitt's Lymphoma".
	C124*	Rottlieb, C et al., International Journal of Cancer, (1996), Vol. 67, pp 724-729, "Structure-Activity Relationship of 17 Structural Analogues of N-Butyric Acid Upon c-myc Expression".
	C125*	Rubio, MA et al., Blood, (1995), Vol. 86, No. 10, pp 3715-3724, "Granulocyte-Macrophage Colony-Stimulating Factor, Phorbol Ester, and Sodium Butyrate Induce the CD11c Integrin Gene Promoter Activity During Myeloid Cell Differentiation".
	C126*	Schrump, DS et al., Clinical Lung Cancer (2002), Vol. 4, No. 3, pp 186-192, "Phase I Study of Sequential Deoxyazacytidine/depsipeptide Infusion in Patients with Malignancies Involving Lungs or Pleura".
	C127*	Vrana JA et al., Oncogene 1999, Vol. 18, pp 7016-7025, "Induction of Apoptosis in U937 Human Leukemia Cells by Suberoylanilide Hydroxamic Acid (SAHA) Proceeds Through Pathways That are Regulated by Bcl-2/Bcl-XL, c-Jun, and p21CIP1, but independent of p53".
↓	C128	Waheed et al. (2000), Proceedings of the American Association for Cancer Research Meeting, (91st, San Francisco, 41:808, Abstract 5135, "The Histone Deacetylase Inhibitor FR 901228 Induces SV40T/T Antigen Expression and P53 Hyperacetylation in Human Pleural Mesothelioma Cells".
MG	C129*	Watanabe, M et al., Cancer Research (1990), Vol. 50, pp 3245-3248, "Effect of liposomes containing sodium butyrate conjugated with anti-CD19 monoclonal antibody on in vitro and in vivo growth of malignant lymphoma".

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
MG	C130	Weiser et al. (2001), J. Immunotherapy, 24:151-61, "Sequential 5-Aza-2'-deoxycytidine-Depsipeptide FR901228 Treatment Induces Apoptosis Preferentially in Cancer Cells and Facilitates Their Recognition by Cytolytic T Lymphocytes Specific for NY-ESO-1".
	C131*	Yu, C et al., Cancer Research (2001), Vol. 63, pp 2118-2126, "Histone Deacetylase Inhibitors Promote STI571-Mediated Apoptosis in STI571-Sensitive and -Resistant Bcr/Abl+ Human Myeloid Leukemia Cells".
	C132*	Zhang, M et al., Cell Stress & Chaperones, (1998), Vol 3, No. 1, pp 57-66, "Heat-Induced Proteolysis of HSF Causes Premature Deactivation of the Heat Shock Response in Nb2 Lymphoma Cells".
	C133	Bruner, RJ et al., Blood (2002), 44th Annual Meeting of the American Society of Hematology, Vol. 100, No. 11, pp Abstract No. 1492, "Phase I trial of the histone deacetylase inhibitor depsipeptide (FR901228) in fludarabine refractory chronic lymphocytic leukemia".
	C134	Guo, F et al., American Society of Hematology, (December 6-10, 2002), p 268b, Abstract 4602 "Co-treatment with the histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA) enhances Apo-2L/TRAIL-induced death inducing signaling complex and apoptosis of human acute lymphoid leukemia cells".
	C135	Heaney, M et al., 2003 ASCO Annual Meeting, Proceedings of the American Society of Clinical Oncology, (2003) Vol. 22, p 577, Abstract 2321, "Clinical experience with the histone deacetylase (HDAC) inhibitor suberoylanilide hydroxamic acid (SAHA) in heavily pre-treated patients with hematological malignancies".
	C136	Marcucci, G et al., Blood, (2002), 44th Annual Meeting of the American Society of Hematology, Vol. 100, No. 11, pp Abstract No. 317, "Phase I trial of the histone deacetylase inhibitor depsipeptide (FR901228) in acute myeloid leukemia (AML)".
	C137	Nimmanapalli, R et al., American Society of Hematology, (December 6-10, 2002), 14 pages, "Co-treatment with the histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA) enhances Gleevec-induced apoptosis of Ber-Abl positive human acute leukemia cells".
	C138	Nimmanapalli, R et al., Blood (2003), Vol. 101, No. 8, pp 3236-3239, "Cotreatment with the histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA) enhances imatinib-induced apoptosis of Bcr-Abl-positive human acute leukemia cells".
↓	C139	Tabe, Y et al., Blood (2002), 44th Annual Meeting of the American Society of Hematology, Vol. 100, No. 11, pp Abstract No. 3028, "Effects of histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA) and DNA methylation inhibitor 5-aza-2'-deoxycytidine (DAC) on the transcriptional activation of RARbeta and p21WAF in acute promyelocytic leukemia cells".
MG	C140	Zhang, C et al, The Journal of Investigative Dermatology (2003), Vol. 121, No. 1, pp Abstract 1189, "The histone inhibitor suberoylanilide hydroxamic acid induces apoptosis in cutaneous T cell lymphoma cells".

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 10/650,025, filed August 26, 2003, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature	/Michel Graffeo/	Date Considered	12/30/2006
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Modified Form 1449/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number	10/616,649
	Filing Date	07/09/03
	First Named Inventor	Chiao
	Group Art Unit	1614
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	24852-501 CIP2

U.S. PATENT DOCUMENTS							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date
MG	A24	6,905,669	06/14/05	DiMartino	424	9.1	04/24/2001

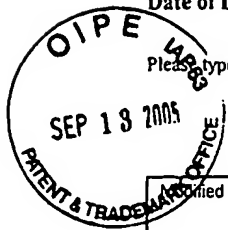
FOREIGN PATENT DOCUMENTS							
Exam Initials	Cite No.	Foreign Patent Document Office	Number	Name of Patentee(s) or Applicant(s)	Date of Publication	English Yes	No
MG	B11	WO	95/31977	Sloan-Kettering Institute for Cancer Research	November 30, 1995	X	
MG	B12	WO	98/55449	The University of Queensland	December 10, 1998	X	
MG	B13	WO	02/085400 A1	SuperGen, Inc.	October 31, 2002	X	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.

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U.S. PATENT DOCUMENTS							
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MG	A20	RE38,506 E	04/20/04	Breslow, et al.	514	316	10/04/1991
MG	A21	2003/0082666	05/01/03	Kammer, et al.	435	18	07/02/2002
MG	A22	2003/0235588	12/25/03	Richon, et al.	424	146.1	02/14/2003
MG	A23	2004/0127522	07/01/04	Chiao, et al.	514	352	07/09/2003

FOREIGN PATENT DOCUMENTS					
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No

OTHER PRIOR ART (NON-PATENT LITERATURE) DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
MG	C81	O'Connor et al. (2001). <i>Journal of the American Society of Hematology</i> 611a, Abstract No. 2562.
MG	C82	Kelly, et al. (2003). <i>Clinical Cancer Research</i> 9:3578-3588.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____ filed _____, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

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MG	A13	6,231,880	05/15/2001	Perrine	424	423	05/29/1998
MG	A14	2004/0002506	12/30/2004	Breslow et al.	514	310	04/01/2004
MG	A15	2004/0087631	05/06/2004	Bacopoulos et al.	514	352	08/26/2003
MG	A16	2004/0122101	06/24/2004	Miller et al.	514	575	06/19/2003
MG	A17	2004/0132825	07/08/2004	Bacopoulos et al.	514	575	10/24/2003
MG	A18	2004/0266818	01/01/2004	Breslow et al.	514	263.4	10/25/2002
MG	A19	2004/0072735	04/15/2004	Richon et al.	514	9	03/04/2003

FOREIGN PATENT DOCUMENTS						
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No	
MG	B10	WO 01/16106	Schering Aktiengesellschaft	03/08/2001		X

OTHER PRIOR ART - NON-PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
MG	C60	Adams and Elliott (2000). <i>Oncogene</i> <u>19</u> : 6687-6692.
	C61	Bates et al. (1999). <i>Proc. American Society of Clinical Oncology</i> <u>18</u> : 180a, Abstract No. 693
	C62	Foster et al. (1997). <i>Invest. New Drugs</i> <u>15</u> : 187-194.
	C63	Gojo et al. (2002). <i>Blood</i> <u>100</u> : Abstract No. 2198.
	C64	Gore and Carducci (2000). <i>Exp. Opin. Invest. Drugs</i> <u>9</u> : 2923-2934.
	C65	Huang and Pardee (2000). <i>Molecular Medicine</i> <u>6</u> : 849-866.
	C66	Johnstone, R. (2002). <i>Nature Reviews Drug Discovery</i> <u>1</u> : 287-299.
	C67	Kelly et al. (2002). <i>Exp. Opin. Invest. Drugs</i> <u>11</u> : 1695-1713.
	C68	Kelly et al. (2002). <i>Proc. American Society of Clinical Oncology</i> <u>21</u> : 6b, Abstract No. 1831.
	C69	Kelly et al. (2001). <i>Proc. American Society of Clinical Oncology</i> <u>20</u> : 87a, Abstract No. 344.
	C70	Kosugi et al. (2001). <i>Jpn. J. Cancer Res.</i> <u>92</u> : 529-536.
	C71	Marshall et al. (2002). <i>J. Exp. Therapeutics and Oncology</i> <u>2</u> : 325-332.
	C72	Piekarz et al. (2001). <i>Blood</i> <u>98</u> : 2865-2868.
	C73	Prakash et al. (2001). <i>Invest. New Drugs</i> <u>19</u> : 1-11.
MG	C74	Rha et al. (1993). <i>J. Korean Med. Sci.</i> <u>8</u> : 251-256.

OTHER PRIOR ART - NON-PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
MG	C75	Rifkind et al. (2002). 224 th ACS National Meeting, Boston, MA, Abstract No. 226.
↓	C76	Sandor et al. (2002). <i>Clinical Cancer Research</i> 8: 718-728.
	C77	Secrist et al. (2003). <i>Curr. Opin. Invest. Drugs</i> 4:1422-1427.
	C78	Summerhayes, M. (2001). <i>J. Oncol. Pharm. Prac.</i> 7: 107-125.
	C79	Vigushin, D. (2002). <i>Current Opin. Invest. Drugs</i> 3: 1396-1402.
MG	C80	Warrell et al. (1998). <i>J. Natl. Cancer Institute</i> 90: 1621-1625.

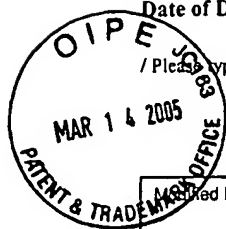
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number	10/616,649
	Filing Date	07/09/03
	First Named Inventor	Chiao
	Group Art Unit	1614
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	24852-501 CIP2

U.S. PATENT DOCUMENTS							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date
MG	A10	6,451,334	09/17/02	Perrine			04/30/01
MG	A11	2003/0161830	08/28/03	Jackson et al.			06/14/02
MG	A12	2004/0127523	07/01/04	Bacopoulos et al.			09/16/03

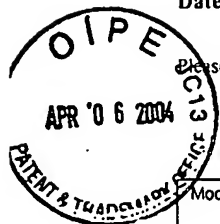
FOREIGN PATENT DOCUMENTS					
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No

NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
MG	C56	International Search Report for PCT/US03/06451, mailed October 27, 2003
MG	C57	International Preliminary Examination Report for PCT/US03/06451, mailed August 3, 2004
MG	C58	International Search Report for PCT/US04/27943, mailed March 7, 2005
MG	C59	Wu et al. (2001). "Negative Regulation of bcl-2 Expression by p53 in Hematopoietic Cells." <i>Oncogene</i> 20(2): 240-251, Abstract, Database CAPLUS on STN, Acc. No. DN134:293668.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____, filed _____, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature	/Michel Graffeo/	Date Considered	12/30/2006
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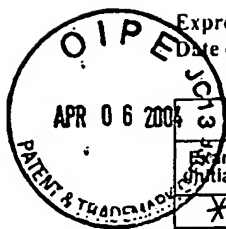
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MG	A1*	5,055,608	10/08/91	Marks et al.	560	169	06/30/89
	A2*	5,175,191	12/29/92	Marks et al.	514	575	05/14/90
	A3*	5,369,108	11/29/94	Breslow et al.	514	266	10/04/91
	A4*	5,608,108	03/04/97	Marks et al.	562	621	04/17/95
	A5*	5,700,811	12/23/97	Breslow et al.	514	314	05/19/94
	A6*	5,773,474	06/30/98	Breslow et al.	514	616	06/07/95
	A7*	5,932,616	08/13/99	Breslow et al.	514	532	04/04/94
	A8*	6,087,367	06/11/00	Breslow et al.	514	266	05/18/99
MG	A9*	6,511,990	01/28/03	Breslow et al.	514	314	08/24/00

FOREIGN PATENT DOCUMENTS							
Exam Initials	Cite No.	Foreign Patent Document Office	Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes	No
X	B1*	WO	98/40080	Beacon Laboratories, L.L.C.	September 17, 1998	X	
	B2*	WO	00/21979	Fujisawa Pharmaceutical Co., LTD	April 20, 2000	X	
	B3*	WO	00/71703	Methylgene, Inc.	November 30, 2000	X	
	B4*	WO	01/18171	Sloan-Kettering Institute for Cancer Research & The Trustees of Columbia University in the City of New York	March 15, 2001	X	
	B5*	WO	01/38322	Methylgene, Inc.	May 31, 2001	X	
	B6*	WO	01/70675	Methylgene, Inc.	September 27, 2001	X	
	B7*	WO	02/22577	Novartis-Erfindungen Verwaltungsgesellschaft M.B.H.	March 21, 2002	X	
	B8*	WO	02/30879	Prolifix Limited	April 18, 2002	X	
	B9*	WO	02/46144	F. Hoffmann-La Roche AG	June 13, 2002	X	

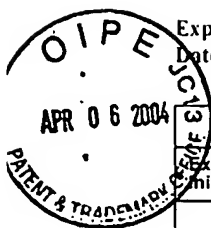
OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
X	C1*	Andrews et al. (2000). <i>Intl. J. Parasitol.</i> 30: 761-768.
	C2*	Archer et al. (1998). <i>Proc. Natl. Acad. Sci. USA</i> 95: 6791-6796.
	C3*	Bhalla et al. (2002). "Co-treatment With The Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid (SAHA) Enhances the Cytotoxic Effects of Gleevec and Arsenic Trioxide (AT) Against Bcr-Abl Positive Human Leukemia Cells." <i>American Society of Hematology, 44th Meeting of the American Society of Hematology, Abstract 4611.</i>
	C4*	Butler et al. (2000). <i>Cancer Res.</i> 60: 5165-5170.
	C5*	Butler et al. (2001). <i>Clinical Cancer Res.</i> 7: 962-970.
	C6*	Butler et al. (2002). <i>Proc. Natl. Acad. Sci. USA</i> 99: 11700-11705.
	C7*	Coffey et al. (2000). <i>Medical and Pediatric Oncology</i> 35: 577-581.

+ Did not receive



OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Exam Officials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
X	C8*	Coffey et al. (2001). <i>Cancer Res.</i> 61: 3591-3594.
I	C9*	Cohen et al. (1999). <i>Anticancer Res.</i> 19: 4999-5006.
I	C10*	Cohen et al. (2002). <i>Anticancer Res.</i> 22: 1497-1504.
I	C11*	Curtin (2002). <i>Exp. Opin. Ther. Patents</i> 12: 1375-1384.
I	C12*	Dressel (2000). <i>Anticancer Res.</i> 20: 1017-1022.
I	C13*	Fei et al. (2002). "Co-treatment With the Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid (SAHA) Enhances Apo-2L/TRAIL-induced Death Inducing Signaling Complex and Apoptosis of Human Acute Lymphoid Leukemia Cells." <i>American Society of Hematology</i> , 44 th Meeting of the American Society of Hematology Abstract No. 4602.
	C14*	Feinman et al. (2002). "The Histone Deacetylase Inhibitor, Suberoylanilide Hydroxamic Acid, Induces Apoptosis of Multiple Myeloma Cells." <i>American Society of Hematology</i> , 44 th Meeting of the American Society of Hematology, Abstract No. 3195.
	C15*	Finnin et al. (1999). <i>Nature</i> 401: 188-193.
	C16*	Furamai et al. (2001). <i>Proc. Natl. Sci. USA</i> 98: 87-92.
	C17*	Grunstein (1997). <i>Nature</i> 389: 349-352.
	C18*	He et al. (2001). <i>J. Clin. Investigation</i> 108: 1321-1330.
	C19*	Hockly et al. (2003). <i>Proc. Natl. Acad. Sci. USA</i> 100: 2041-2046.
I	C20*	Kelly et al. (2001). "Suberoylanilide Hydroxamic Acid (SAHA), a Histone Deacetylase Inhibitor: Biologic Activity Without Toxicity." <i>American Society of Clinical Oncology</i> , Abstract No. 344.
X	C21*	Kelly et al. (2002). "Histone deacetylase inhibitor, suberoylanilide hydroxamic acid (SAHA), orally administered has good bioavailability and biologic activity." <i>American Society of Clinical Oncology</i> , 38 th Annual Meeting of the American Society of Clinical Oncology, November 7-10, 2002, Abstract No. 1831.
	C22*	Kelly et al. (2002). "A phase I clinical trial of an oral formulation of the histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA)." <i>European J. Cancer</i> 38(Suppl. 7): 88, Abstract No. 286.
	C23*	Kim et al. (1999). <i>Oncogene</i> 18: 2461-2470.
I	C24*	Kohge et al. (1998). <i>Biochem. Pharmacol.</i> 56: 1359-1364.
	C25*	Komatsu et al. (2001). <i>Cancer Res.</i> 61: 4459-4466.
	C26*	Kouraklis and Theocharis (2002). <i>Curr. Med. Chem. Anti-Cancer Agents</i> 2: 477-484.
	C27*	Lee et al. (2001). <i>Cancer Res.</i> 61: 931-934.
	C28*	Lin et al. (1998). <i>Nature</i> 391: 811-814.
	C29*	Mai et al. (2001). <i>OPPI Briefs</i> 33: 391-394
I	C30*	Marks et al. (2000). <i>J. of the Natl. Cancer Institute</i> 92: 1210-1215.
I	C31*	Marks et al. (2001). <i>Clinical Cancer Res.</i> 7: 759-760.
	C32*	Marks et al. (2001). <i>Curr. Opin. In Oncology</i> 13: 477-483.
	C33*	Marks et al. (2001). <i>Nature Reviews</i> 1: 194-202.
	C34*	Miller et al. (2003). <i>J Med Chem.</i> 46: 5097-5116.
	C35*	Munster et al. (2001). <i>Cancer Res.</i> 61: 8492-8497.
	C36*	O'Connor et al. (2002). "Clinical experience of the histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA) in heavily pre-treated patients with aggressive non-hodgkin's lymphoma (NHL0 and hodgkin's disease (HD))." <i>American Society of Clinical Oncology</i> , December 6-10, 2002, Abstract No. 4742.
	C37*	Qui et al. (2000). <i>Mol. Biol. Cell</i> 11: 2069-2083.
	C38*	Richon et al. (1996). <i>Proc. Natl. Acad. Sci. USA</i> 93: 5705-5708.
	C39*	Richon et al. (1998). <i>Proc. Natl. Acad. Sci. USA</i> 95: 3003-3007.
	C40*	Richon et al. (2000). <i>Proc. Natl. Acad. Sci. USA</i> 97: 10014-10019.
I	C41*	Richon and O'Brien (2002). <i>Clinical Cancer Res.</i> 8: 662-664.
	C42*	Saito et al. (1999). <i>Proc. Natl. Acad. Sci. USA</i> 96: 4592-4597.
X	C43*	Sgouros et al. (2002). "Synergistic Interaction of Suberoylanilide Hydroxamic Acid (SAHA) and

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
		Radiation in Human Prostate Tumor Spheroids." <i>American Society of Clinical Oncology</i> , Abstract No. 105.
*	C44*	Stowell et al. (1995). <i>J. Med. Chem.</i> 38: 1411-1413.
	C45*	Su et al. (2000). <i>Cancer Res.</i> 60: 3137-3142.
	C46*	Suzuki et al. (1999). <i>J. Med. Chem.</i> 42: 3001-3003.
	C47*	Van Lint et al. (1996). <i>Gene Expression</i> 5: 245-253.
	C48*	Vrana et al. (1999). <i>Oncogene</i> 18: 7016-7025.
	C49*	Webb et al. (1999). <i>J. Biol. Chem.</i> 274: 14280-14287.
	C50*	Yoshida et al. (1990). <i>J. Biol. Chem.</i> 265: 17174-17179.
	C51*	Yoshida et al. (1995). <i>BioEssays</i> 17: 423-430.
	C52*	Zhou et al. (1999). <i>Gene</i> 233: 13-19.
	C53*	Zhou et al. (2000). <i>Proc. Natl. Acad. Sci. USA</i> 97: 1056-1061.
	C54*	Zhou et al. (2000). <i>Proc. Natl. Acad. Sci. USA</i> 97: 14329-14333.
	C55*	Zhou et al. (2001). <i>Proc. Natl. Acad. Sci. USA</i> 98: 10572-10577.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 10/379,149, filed March 4, 2003, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature	/Michel Graffeo/	Date Considered	12/30/2006
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